

FISCAL NOTE

SB 115 - HB 81

April 11, 2005

SUMMARY OF BILL: Prohibits clinical trials involving pharmaceuticals at state hospitals and higher education institutions unless the institutional review boards at those state hospitals and higher education institutions make the results of the trial public records that are made available to physicians and the public and the trial is registered with the National Institutes of Health website (www.ClinicalTrials.gov). Rulemaking authority is vested with the Tennessee Higher Education Commission and the Department of Health. The rules may provide appropriate protections of information that is confidential under state or federal law.

ESTIMATED FISCAL IMPACT:

Increase State Expenditures – \$30,750

Decrease State Revenues – Exceeds \$100,000

Assumptions:

- Administrative cost of approximately \$31,000 to track and enter trials into online database at UT and TBR institutions.
- Potential loss of revenue for both UT and TBR systems. This loss of revenue is due to the loss of sponsored research as a result of firms wanting to protect their proprietary interests. The specific loss of revenue cannot be readily determined, but is estimated to exceed \$100,000 for each system.

CERTIFICATION:

This is to duly certify that the information contained herein is true and correct to the best of my knowledge.



James W. White, Executive Director